URGENT – UPDATED VOLUNTARY DEVICE CORRECTION

DO NOT USE VALLEYLAB FORCE FX-C OR SSE2L ELECTROSURGERY UNITS WHEN SUPPORTING A PATIENT WITH THE CENTRIMAG BLOOD PUMPING SYSTEM

July 24, 2008

Dear Doctor: **[Chief of Cardiothoracic Surgery]**

The purpose of this updated device correction notice is to follow up regarding the Voluntary Device Correction Notice that was sent to you dated March 17, 2008. The original device correction notice described two independent events where use of the Valleylab Force FX-C Electrosurgery Unit (ESU) triggered a "Motor Fail" Alarm and stoppage of the CentriMag Blood Pumping System in a patient in Argentina and a second patient in the United Kingdom. The objective of this updated device correction notice is to provide: 1) further information regarding the risk to the patient should the Pump stop due to interference from the Valleylab Force FX-C or SSE2L ESUs, and 2) an updated recommendation for corrective action.

The CentriMag Blood Pumping System provides mechanical circulatory support. While Levitronix is unaware of any patient injury or death associated with the use of Valleylab Force FX-C or SSE2L ESUs, cessation of pumping may lead to inadequate blood flow and the potential for negative clinical sequelae including death, thromboembolism, stroke, neurologic dysfunction, and end organ failure. Based on the potential risk to the patient, Levitronix is issuing a new Warning related to use of the Valleylab Force Valleylab Force FX-C or SSE2L ESUs:

WARNING

Do not use the Valleylab Force FX-C or Valleylab SSE2L ESUs on a patient supported with the CentriMag Blood Pumping System. Use of these ESUs may result in stoppage of the pump and potentially cause serious injury or death.

Should pump stoppage occur, clamp the Pump outflow line, turn the CentriMag Console OFF then ON and verify that the system is operating. If the CentriMag Console fails to operate properly, switch to the CentriMag Back-Up Console and Motor. Once the CentriMag System is operational, unclamp the outlet tubing and resume support.

However, be aware that stoppage of the pump may reoccur unless an alternative electrosurgical unit or blood pump is used.

This Warning supersedes the previous Warning communicated to you regarding the use of Valleylab Force FX-C or SSE2L ESUs in the March 17, 2008 Voluntary Device Correction Notice.

Please distribute this letter to the Risk Management group and all individuals responsible for the surgical and medical management of patients being supported by the CentriMag Blood Pumping System. This should include surgeons, anesthesiologists, perfusionists, biomedical engineers, nurses and any other staff in the operating room and intensive care settings.

MedWatch Reporting

Adverse reactions or quality problems related to this product or any FDA approved product may be made to FDA's MedWatch, the agency's voluntary reporting program, by e-mail at www.fda.gov/medwatch/report.htm, or by phone at 800-332-1088, or by fax to 800-332-0178. Also reports of adverse events can be mailed to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20852-9787.

Levitronix recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern.

Sincerely,

Susan K. Hamann

Susan Hamann
Regulatory Affairs Manager
Levitronix LLC

If you have any questions or need further assistance please contact:

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VOLUNTARY DEVICE CORRECTION NOTICE REPLY FORM

PLEASE COMPLETE AND RETURN THIS FORM TO LEVITRONIX ASAP.

PRODUCT: **Levitronix/Thoratec CentriMag System**

LOT/SN NO.: **ALL**

Name and address of the Hospital	
The departments and individuals informed of this Device Correction Notice (check all that apply)	☐ Risk Management ☐ Chief of Cardiothoracic Surgery ☐ Anesthesiologists ☐ Perfusionists ☐ Director of Nursing ☐ Biomedical Engineering ☐ Other (please specify) _____
Name and title of the individual completing this form	
Signature of the individual completing this form (this signature represents that you have read and understood the contents of the Notice)	
Date this form was completed	

Please mail, fax or scan/email the completed form to:

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